

Apparatus and methods for non-invasively determining cardiac output using partial re-breathing techniques are disclosed in which the apparatus is constructed with an instantaneously adjustable deadspace (70) for accommodating differences in breathing capacities various patients. The apparatus (50) is constructed of inexpensive elements, including a single two-way valve (22) which renders the apparatus very simple to use and inexpensive so that the unit may be readily disposable. The method of the invention provides a novel means (46) of estimating cardiac output based on alveolar CO₂ values rather than end-tidal CO₂ values as previously practiced. A program for calculating cardiac output is also disclosed.

APPARATUS AND METHOD FOR NON-INVASIVELY MEASURING CARDIAC OUTPUT

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BACKGROUND

Field of the Invention: This invention relates to non-invasive means of determining cardiac output in patients, and specifically relates to partial re-breathing systems and methods for determining cardiac output in patients.

Statement of the Art: It is important in many medical procedures to
10 determine or monitor the cardiac output of a patient. Techniques are known and used in the art which employ the use of catheters inserted at certain arterial points (e.g., femoral artery, jugular vein, etc.) to monitor blood temperature and pressure
in order to determine cardiac output of the patient. Although such techniques can produce a reasonably accurate result, the invasive nature of the procedure has high
15 potential for morbidity and mortality consequences.

Adolph Fick's measurement of cardiac output, first proposed in 1870, has served as the standard by which all other means of determining cardiac output have been evaluated since that date. Fick's well-known equation, written for CO₂, is:

$$Q = \frac{V_{CO_2}}{(C_{vCO_2} - C_{aCO_2})}$$

20 where Q is cardiac output, V_{CO₂} is the amount of CO₂ excreted by the lungs and C_{aCO₂} and C_{vCO₂} are the arterial and venous CO₂ concentrations, respectively.

Notably, the Fick Equation presumes an invasive method (i.e., catheterization) of calculating cardiac output because the arterial and mixed venous blood must be sampled in order to determine arterial and venous CO₂ concentrations.

25 It has previously been shown, however, that non-invasive means may be used for determining cardiac output while still using principles embodied in the Fick Equation. That is, expired CO₂ ("pCO₂") levels can be monitored to estimate arterial CO₂ concentrations and a varied form of the Fick Equation can be applied to evaluate observed changes in pCO₂ to estimate cardiac output. One use of the Fick
30 Equation to determine cardiac output in non-invasive procedures requires the

Thus, it would be advantageous to provide a means of measuring cardiac output using partial re-breathing techniques which 1) overcome the disadvantages of prior systems, 2) provide better and more continuous measurement, and 3) require less expensive equipment thereby making the device suitable for manufacturing as a single-use, or disposable, product. It would also be advantageous to provide partial re-breathing apparatus which is instantaneously adjustable to compensate for various sizes and capacities of patients. Further, it would be advantageous to provide new methods of estimating cardiac output based on alveolar CO₂ output rather than end tidal CO₂ as is currently used in the art.

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SUMMARY OF THE INVENTION

In accordance with the present invention, apparatus and methods for measuring cardiac output using a modified Fick Equation are provided where the amount of deadspace which is provided in the apparatus can be adjusted to increase or decrease the volume of exhalate to be re-breathed by the patient, thereby decreasing ventilation without changing airway pressure. The apparatus and methods of the present invention also provide an adjustability factor which enables the apparatus to be adjusted to suit any size or capacity of patient. The apparatus of the present invention also employs significantly less expensive elements of construction thereby rendering the device disposable.

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The apparatus and methods of the present invention apply a modified Fick Equation to calculate changes in pCO₂ flow and concentration to evaluate cardiac output. The traditional Fick Equation, written for CO₂ is:

$$Q = \frac{V_{CO_2}}{(C_{vCO_2} - C_{aCO_2})}$$

where Q is cardiac output (when calculated using re-breathing techniques referred to as pulmonary capillary blood flow or "PCBF"), V_{CO₂} is the output of CO₂ from the lungs and C_{aCO₂} and C_{vCO₂} are the arterial and venous CO₂ concentrations, respectively. It has been shown in prior work of others that cardiac output can be

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commensurate with the requirements of differently sized patients. In one embodiment of the ventilation apparatus, selectively adjustable deadspace is provided through which the patient exhales and inhales. Thus, the adjustable deadspace of the apparatus permits easy adjustment of the deadspace to
5 accommodate any size or capacity of patient, from a small to a large adult. As a result, the patient is provided with a volume of re-breathable gas commensurate with the patient's size which decreases effective ventilation without changing the airway pressure. Because airway and intra-thoracic pressure are not affected by the re-breathing method of the present invention, cardiac output is not significantly
10 affected by re-breathing. In an alternative method, the deadspace may be ~~effectively lessened by selectively leaking exhaled gas from the ventilation system to~~ atmosphere or to a closed receptacle means during inspiration.

The ventilation apparatus of the present invention includes a tubular portion which is placed in contact with the patient, and an inhalation conduit and exhalation
15 conduit. In a common configuration, the inhalation conduit and exhalation conduit may be interconnected between a ventilator unit and the patient. Alternatively, however, a ventilator unit (i.e., a source of deliverable gas mechanically operated to assist the patient in breathing) need not be used with the ventilation apparatus and inhaled and exhaled breath is merely taken from or vented to atmosphere. Other
20 conventional equipment commonly used with ventilator units or used in ventilation of a patient may be used with the inventive ventilation apparatus, such as a breathing mask.

An electrical pneumotachometer for measuring flow of gas and a capnograph for measuring CO₂ concentrations are provided in proximity to the tubular portion
25 between the inhalation and exhalation portions of the ventilation apparatus and the patient's lungs. The pneumotachometer and capnograph serve as detection apparatus for detecting changes in gas concentrations and flow and are in electrical communication with a computer having software designed to store and evaluate the measurements taken by the detection apparatus in real time. Other forms of
30 detection apparatus may be used. Adjustable deadspace means are provided in connection with the exhalation portion of the ventilation apparatus, and may interconnect with the inhalation portion of the ventilation apparatus. In one embodiment, the adjustable deadspace means may be manually adjusted.

which partial rebreathing occurs and during which normal breathing occurs may be determined by the individual size and lung capacity of the patient. Additionally, the period of time between a rebreathing episode and a subsequent normal breathing episode may vary between patients depending on a particular patient's size and
5 breath capacity. Thus, a thirty second time period for a breathing episode is only an average time and may be greater or lesser.

Cardiac output is determined, in the present invention, by estimating alveolar CO_2 concentration rather than basing output on end-tidal CO_2 concentration, as is practiced in the prior art. Partial pressure values that are obtained from CO_2
10 measurements are converted to a value for gas content in the blood using the dissociation equation known in the art. ~~Thus, a more accurate cardiac output can be~~ determined. In addition, the accuracy of cardiac output is increased by correcting VCO_2 values to account for flow of CO_2 into the functional residual capacity of the lungs, defined as the volume of gas left in the lungs at the end of an expired breath.
15 The determination of values based on experiential data are processed by the software program to determine cardiac output.

The ventilation apparatus of the present invention employs inexpensive yet accurate monitoring systems as compared to the systems currently used in the art. The methods of the invention allow automatic adjustability of the apparatus for
20 accommodating patients of different sizes and provides consistent monitoring with modest recovery time. Further, the present apparatus and methods can be used equally with non-responsive, intubated patients as well as non-intubated, responsive patients.

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BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, which illustrate what is currently considered to be the best mode for carrying out the invention:

FIG. 1 is a schematic representation of conventional ventilation systems used for assisting patient breathing;

30 FIG. 2 is a schematic representation of prior art re-breathing systems;

FIG. 3 is a schematic first embodiment of the ventilation apparatus of the present invention illustrating an adjustably expandable deadspace;

hose 18 and an expiratory hose 20. Both the inspiratory hose 18 and expiratory hose 20 are connected to a ventilator machine (not shown) which delivers air to the inspiratory hose 18. A one-way valve 22 is positioned on the inspiratory hose to prevent exhaled gas from entering the inspiratory hose 18 beyond the valve 22. A
5 similar one-way valve 24 on the expiratory hose 20 limits movement of inspiratory gas into the expiratory hose 20. Exhaled air flows passively into the expiratory hose 20.

In known re-breathing ventilation circuits 30, as shown in FIG. 2, the tubular portion 32 is inserted into the trachea of the patient by intubation
10 procedures, and gas is provided to the patient from a ventilator machine (not shown) via an inspiratory hose 34 which is interconnected by a Y-piece 36 to an expiratory hose 38. An additional length of hose 40 is provided between the tubular portion 32 and the Y-piece 36 which acts as a deadspace for receiving exhaled gas. A three-way valve 42 generally positioned between the Y-piece 36 and the opening to
15 the additional length of hose 40 is constructed for intermittent actuation to selectively direct the flow of gas. That is, at one setting, the valve 42 allows inspiratory gas to enter the tubular portion 32 while preventing movement of the gas into the additional length of hose 40. In a second setting, the valve 42 allow exhaled gas to enter into the expiratory hose 38 while preventing movement of gas
20 into the additional length of hose 40. In a third setting, the three-way valve 42 directs exhaled air to enter into the additional length of hose 40 and causes the patient to re-breathe the exhaled air on the following breath to thereby cause a change in effective ventilation.

The change in VCO_2 and end-tidal CO_2 caused by the change in ventilation
25 in the prior art system of FIG. 2 can then be used to calculate cardiac output. Sensing and/or monitoring devices may be attached to the re-breathing ventilation circuit 30 between the additional length of hose 40 and the tubular portion 32. The sensing and/or monitoring devices may include, for example, means 44 for detecting CO_2 concentration and means 46 for detecting flow parameters during
30 inhalation and exhalation. Those sensing and/or monitoring devices are typically connected to data recording and display equipment (not shown). One problem encountered in use of the prior art system is that the deadspace provided by the additional length of hose 40 is fixed and may not be adjusted. As a result, the

deadspace are available, extending the length of the hose 60 being but one approach. A three-way valve 68 may be connected to the additional length of hose 60 to force inspiratory gas to enter the deadspace 70 upon inhalation. The three-way valve 68 is also structured to selectively prevent exhaled gas from entering the deadspace 70 during normal breathing or to direct exhaled gas into deadspace 70 during re-breathing episodes so that the patient is forced to re-breathe exhaled gas from the deadspace 70.

A flow meter 72, or pneumotachometer, is attached to the ventilation apparatus 50 at a point between the tubular air-way 52 and the additional length of hose 60. The flow meter 72 detects gas flow through the ventilation apparatus 50.

A CO₂ sensor 74, or capnograph, is also connected to the ventilation apparatus 50 between the tubular air-way 52 and the additional length of hose 60. The CO₂ sensor 74 detects changes in CO₂ resulting from a change in ventilation, the data from which is used to calculate cardiac output. The CO₂ sensor 74 may be an "on airway" sensor, a sampling sensor of the type which withdraws a side stream sample of gas for testing, or any other suitable CO₂ sensor. Both the flow meter 72 and CO₂ sensor 74 are connected to a computer 76 which is programmed to store and analyze data from the flow meter 72 and CO₂ sensor 74, and to calculate from the data the estimated cardiac output of the patient.

As previously described herein, the differential Fick Equation requires a change in pulmonary gas concentration and output to be induced in the patient in order to estimate cardiac output. Re-breathing gas previously exhaled by the patient increases the amount of CO₂ breathed in by the patient and enables the evaluation of increased CO₂ levels during a change in effective ventilation as compared to standard CO₂ levels during normal ventilation. The ventilation apparatus of the present invention provides the ability to selectively adjust the deadspace required in re-breathing to increase the amount of gas (CO₂) re-breathed by the patient from the previous exhalation. The ventilation apparatus of the present invention also allows the ventilation circuit to be adjusted automatically in accordance with the size or capacity of a patient, and in response to ventilation parameters. That is, if the detected change in etCO₂ is less than 3 mm Hg, or the change in VCO₂ is less than 0.2 times the VCO₂, then the deadspace volume should be increased by twenty percent.

section 90, 92 may be made from corrugated plastic material the length of which can be easily expanded or contracted, and the plastic material will maintain its adjusted length until repositioned. The embodiment of FIG. 6 provides a particularly simple and inexpensive construction rendering a particularly preferred embodiment because of its ease of use and disposability.

In yet another embodiment of the ventilation apparatus 50 of the present invention, as shown in FIG. 7, the amount of available deadspace 70 may be selectively adjusted by providing a plurality of shunt lines 84, 94, 96 positioned between the inspiratory hose 54 and the expiratory hose 56, with each shunt line 84, 94, 96 being structured with a two-way shunt valve 86, 98, 100. In operation, the amount of deadspace 70 required, as dictated by the size or capacity of the patient, may be selectively provided by using any suitable number of shunt lines 84, 94, 96 to allow exhaled gas to move through the ventilation apparatus 50. For example, given a patient of average size or lung capacity, it may be appropriate to use the first shunt line 84 and the second shunt line 94 as potential deadspace 70. Thus, as the patient exhales in a re-breathing episode, the shunt valves 86, 98 associated with the first shunt line 84 and second shunt line 94 may be opened allowing exhaled and re-breathable gas to fill the expiratory hose 56, the inspiratory hose 54 between the second shunt line 94 and the Y-piece 58, the first shunt line 84 and the second shunt line 94. With a patient of larger size or greater lung capacity, it may be necessary to use the third shunt line 96 as well in providing sufficient deadspace 70 for re-breathing. Notably, each shunt valve 86, 98, 100 may be in electromechanical communication with the computer 76 (not shown in FIG. 7) so that the computer may determine, from the pneumotachometer, for example, that additional deadspace 70 is required and cause the opening of one or more of the shunt valves 86, 98, 100 to provide sufficient additional deadspace 70. In an alternative embodiment, the ventilation apparatus 50 shown in FIG. 7 may be modified by the addition of selectively expandable sections 90, as shown in FIG. 6.

In the several alternative embodiments of the invention previously illustrated and described, the amount or volume of the deadspace has been selectively adjustable by providing means for adjusting the volume of the deadspace, such as by providing length expanding means. It may be equally appropriate, however, to provide a change in ventilation, as required by the differential Fick Equation, by

expiratory hose 56 is structured with a flow meter line 72 attachable to a flow meter (not shown) and a CO₂ sensor 74 for collecting data derived during a re-breathing event. In the illustrated TGI apparatus 120, the endotracheal tube 122 provides deadspace 70 required for re-breathing in addition to the ventilation circuit 136 as previously described. To act as a deadspace, however, the TGI apparatus (i.e., the gas source 128 and flow meter 132) must be turned off, reduced or otherwise disabled. Exhaled air is thereby allowed to fill the endotracheal tube 122 and enter through the Y-piece 58. The endotracheal tube 122 and ventilation circuit 136 serve as deadspace when the TGI apparatus 120 is turned off. The volume of deadspace provided by the TGI apparatus configuration may be further increased or decreased, as necessary, by varying the depth to which the catheter 126 is positioned in the patient's trachea.

The computer to which the flow meter 72 and CO₂ sensor 74 are connected is programmed to receive data collected by the flow meter 72 and CO₂ sensor 74 and to analyze the data to calculate an estimated cardiac output. The parameters which are required by the software program to analyze the data and to estimate cardiac output are described hereafter.

The calculation of cardiac output for a given patient is based on the collection of data from the CO₂ sensor and flow monitor attached to the ventilation apparatus of the present invention. Raw flow and CO₂ signals from the flow monitor and CO₂ sensor are filtered to remove artifacts and the flow signals, CO₂ signals and pressure signals are stored in a buffer in the software program. When the flow signal crosses a prescribed threshold (e.g., 15 liters/minute), the buffer is searched to find the most recent zero-crossing. The zero-crossing is identified as the start of a new breath. All data stored in the buffer since the last zero-crossing and the crossing of the prescribed threshold (i.e., the new zero-crossing) is established as one breathing cycle. For each breathing cycle, the parameters of the breathing phase are calculated as follows:

- 1) **etCO₂**: The average concentration of CO₂ during the final 5% of expiratory tidal volume is taken as end-tidal CO₂.
- 2) **VCO₂**: The integral of flow (in milliliters) multiplied by concentration of CO₂ over the entire breath is VCO₂.

perfused alveoli 162 which comprises parallel deadspace (PDS), so called because it is ventilated in parallel with the perfused alveoli.

In the present invention, the software program compensates, or accounts, for the functional residual capacity of the patient's lungs and the alveolar deadspace
5 which exists. The correction is equal to the FRC times the change in end tidal concentration or

$$VCO_2 = VCO_2 + FRC \times \Delta etCO_2 / Pbar,$$

where "Pbar" is barometric pressure. FRC is estimated as a function of body weight as estimated by the deadspace volume using the equation

$$10 \quad FRC = FRC\text{-factor} \times \text{airway deadspace} + \text{an off-set value},$$

where the FRC-factor is a value experimentally determined or is based on published

data known in the art and the off-set value is a fixed constant which is added to compensate for breathing masks or other equipment components which may add deadspace to the circuit and thereby unacceptably skew the relationship between
15 FRC and deadspace. The airway deadspace is the volume at which CO_2 crosses a selected threshold [e.g., $0.5etCO_2$]. Dry gas is assumed in all equations.

Compensation is also made for parallel deadspace (See FIG. 10). Parallel dead space CO_2 concentration is calculated as a low pass filtered version of the mixed inspired CO_2 plus the airway deadspace times the previous end tidal CO_2
20 concentration. The average CO_{2PDS} is $etCO_2$ times airway deadspace plus inspired CO_2 volume divided by the tidal volume. Breath-by-breath calculation of parallel deadspace, or unperfused space, concentration is therefore:

$$CO_{2PDS}(n) = [FRC / (FRC + V_t)] \times CO_{2PDS}(n-1) + ([V_{iCO_2} + \text{deadspace} \times etCO_2(n-1)] / V_t) \times [V_t / (V_t + FRC)]$$

25 where V_t is the tidal volume (the volume of the breath), PDS is parallel deadspace (i.e., space in the lung that is ventilated but not perfused by blood flow), $etCO_2$ is the concentration of CO_2 at the end of the exhaled breath, or "end-tidal," "dead space" is the volume in the trachea and bronchi through which air must pass to get to the alveoli but in which no gas exchange occurs (also defined as "serial dead
30 space," See FIG. 10) and (n-1) indicates the previous breath.

Alveolar CO_2 partial pressure (" PA_{CO_2} ") is calculated from the end-tidal CO_2 and the CO_2 in the parallel deadspace. Thus, if

The operation logic of the software program is briefly illustrated in the flow chart of FIG. 11. The computer is programmed to detect the end of an exhalation 200 at which point the computer collects data from the CO₂ sensor and the flow meter and calculates CO₂, VCO₂, Inspired CO₂ and airway deadspace values 202.

5 The program then calculates FRC, at 204, according to the equation previously noted. The program also corrects the VCO₂ value, at 206, in accordance with the equation previously described. At thirty second intervals (thirty seconds only being an average time, which may be adjusted higher or lower commensurate with the size of the patient), the CO₂ and VCO₂ values are re-calculated, at 210, to provide

10 an average of those values based on time, not on the variable time at which exhalation may end.

The program then calculates the estimated pCO₂ in the parallel deadspace 212 and calculates the estimated pCO₂ in the alveoli 214 using the equations previously described. At that point, a re-breathing episode is initiated 216 and a

15 deadspace is introduced. Again, the computer collects data from the CO₂ sensor and the flow monitor of the apparatus and from that data, the change in VCO₂ and alveolar CO₂ induced by the introduction of the deadspace is calculated 218. If the calculated change in VCO₂ is less than twenty percent (20%) of the baseline VCO₂ or if the change in partial pressure of alveolar CO₂ is less than 3mm Hg 220, then

20 the operator is notified to increase the partial re-breathing deadspace 222 by increasing the expandable volumetric dimension of the adjustable deadspace of the apparatus. Baseline values are cancelled 224 then recalculated, as suggested by arrow 226. If, however, the change in VCO₂ during re-breathing is greater than 80% of baseline values, then the operator is notified to decrease the adjustable

25 deadspace of the apparatus by decreasing the volumetric dimension of the adjustable deadspace 230. The baseline values are cancelled 232 and recalculated, as suggested by arrow 234. Notably, the computer may notify the operator to make the necessary changes in the adjustable deadspace or, in an alternative embodiment, the computer may signal mechanical means connected to the adjustable deadspace to

30 increase or decrease the volumetric dimension of the deadspace automatically.

Upon proper adjustment of the adjustable deadspace and the recalculation of baseline CO₂, VCO₂, inspired CO₂ and airway deadspace values, the alveolar partial pressure (etCO₂) is converted by the software program to CO₂ content and the

CLAIMSWhat is claimed is:

1. Apparatus for non-invasive determination of cardiac output comprising:
 - 5 an airway conduit for contact with a patient's airway;
an inspiratory conduit interconnected to said airway conduit;
an expiratory conduit interconnected to said airway conduit;
a volume-adjustable deadspace positioned in fluid communication with said
expiratory conduit; and
 - 10 detection apparatus positioned in proximity to said airway conduit for detecting
~~changes in gas concentrations and gas flow from said patient.~~
2. The apparatus of claim 1 wherein said volume-adjustable deadspace includes at least one shunt line extending between said expiratory conduit and said
15 inspiratory conduit, said shunt line being structured with a selectively actuated shunt valve providing movement of exhaled gas between said inspiratory conduit and said expiratory conduit via said shunt line.
3. The apparatus of claim 2 further comprising a source of ventilation in
20 communication with said airway conduit to provide gas to a patient.
4. The apparatus of claim 2 further comprising a plurality of shunt lines extending between said expiratory conduit and said inspiratory conduit, each said shunt line having a selectively actuated shunt valve providing movement of exhaled
25 gas between said inspiratory conduit and said expiratory conduit.
5. The apparatus of claim 2 wherein said expiratory conduit includes a volume-expandable section and said inspiratory conduit includes a volume-expandable section, each said volume-expandable section being positioned to
30 selectively expand said volume-adjustable deadspace.
6. The apparatus of claim 5 further comprising a source of ventilation in communication with said airway conduit to provide gas to a patient.

15. The apparatus of claim 1 wherein said adjustable deadspace is an expandable section of conduit positioned between said airway conduit and a source of ventilation gas.

5 16. The apparatus of claim 1 wherein said volume-adjustable deadspace includes an evacuation line connected to said expiratory conduit, said evacuation line having gas releasing structure for evacuating gas from said evacuation line for reducing the volume of said deadspace.

10 17. The apparatus of claim 16 further comprising a compliant receptacle attached to said evacuation line for receiving evacuated exhaled gas therein.

18. The apparatus of claim 1 wherein said volume-adjustable deadspace is provided by a tracheal gas insufflation device.

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19. Apparatus for non-invasively determining cardiac output of a patient comprising an airway conduit for contact with a patient's airway, an inspiratory conduit connected to said airway conduit and an expiratory conduit connected to said airway conduit, said expiratory conduit being structured with an evacuation line
20 for selectively evacuating an amount of exhaled gas from said patient and a selectively-adjustable valve connected to said evacuation line for releasing an amount of exhaled gas through said evacuation line.

20. The apparatus of claim 19 further comprising an evacuation port for
25 releasing gas, and further comprising a compliant receptacle connected thereto for receiving said exhaled gas.

21. The apparatus of claim 19 further comprising a source of ventilation in communication with said airway conduit to provide gas to a patient.

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22. Apparatus for non-invasively determining cardiac output of a patient comprising an airway conduit for contact with a patient's airway, a source of gas in communication with said airway conduit, a gas insufflation conduit extending from

concentration, gas concentration over inhalation and exhalation and gas concentration during inspiration;
redetermining said gas concentration to account for parallel deadspace; and
calculating the difference between said baseline gas concentrations and volume of
5 gas output with the detected change in gas concentration and gas volume output following re-breathing.

24. The method according to claim 23 wherein said dead space of said ventilation apparatus is volume-adjustable, said method further comprising:
10 adjusting said volume-adjustable deadspace of said ventilation apparatus responsive to a perceived variance from a selected value of gas concentration per
volume of gas prior to repeating said normal breathing.

25. The method according to claim 24 wherein said measured gas is CO₂
15 expelled from said lungs of said patient.

26. The method according to claim 25 wherein said adjusting of said volume-adjustable deadspace comprises expanding the volume of said deadspace responsive to a perceived value of expelled gas volume less than twenty percent of
20 said baseline value of expelled gas volume.

27. The method according to claim 25 wherein said adjusting of said volume-adjustable deadspace comprises expanding the volume of said deadspace responsive to a perceived change in value of said alveolar gas concentration less
25 than 3mm Hg partial pressure.

28. The method according to claim 25 wherein said adjusting of said volume-adjustable deadspace comprises decreasing the volume of said deadspace responsive to a perceived value of greater than eighty percent of said baseline
30 expelled gas volume.

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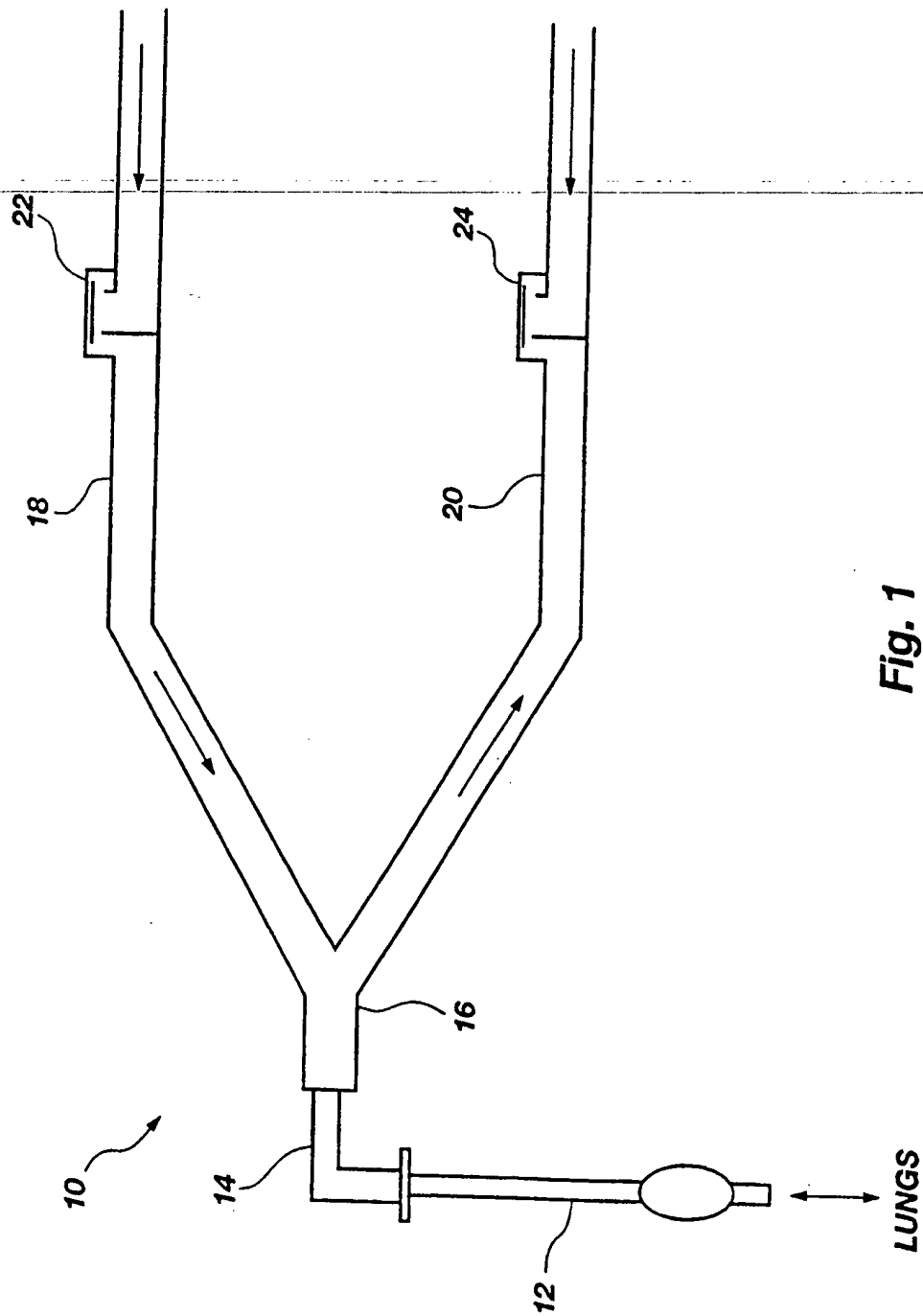


Fig. 1
(PRIOR ART)

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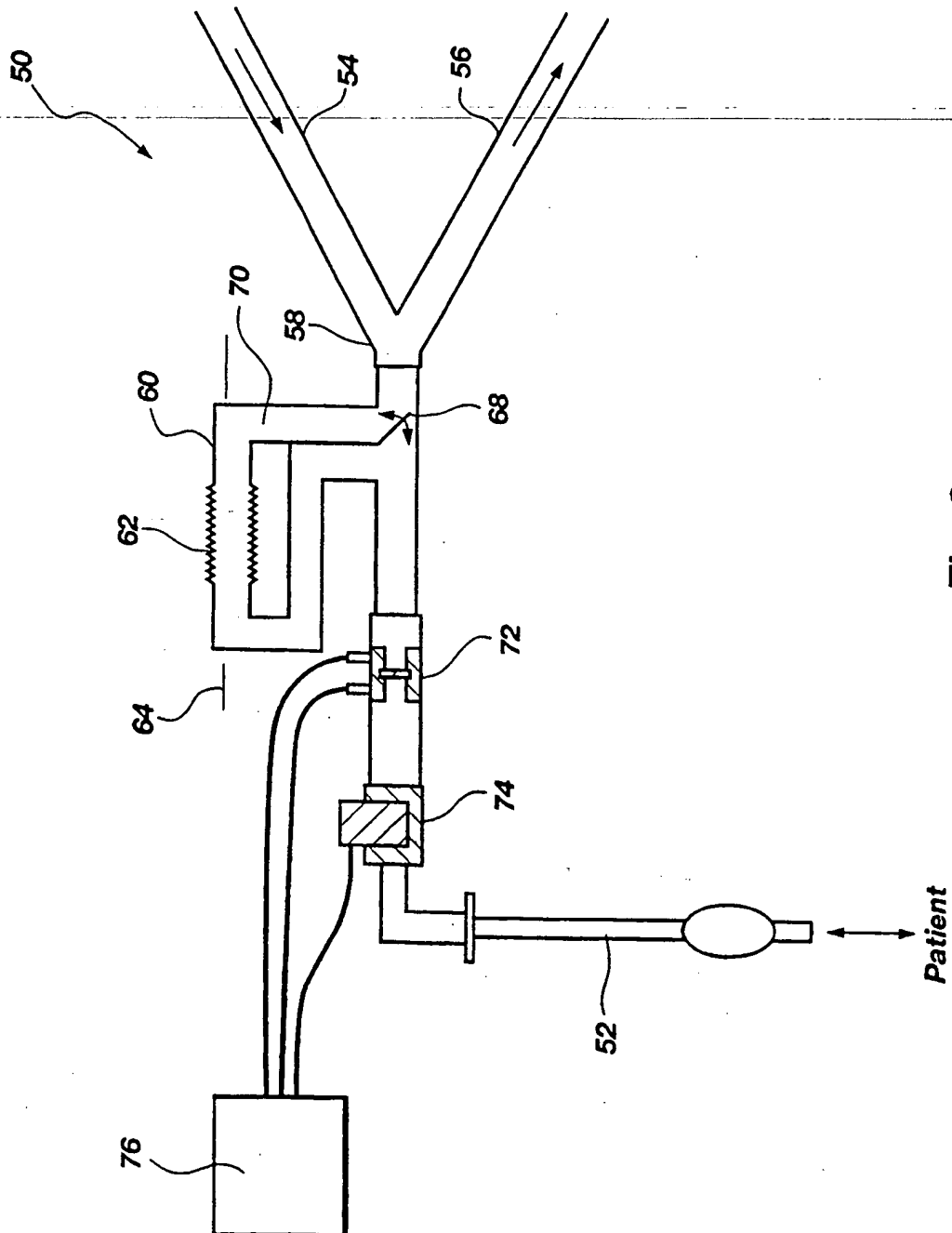


Fig. 3

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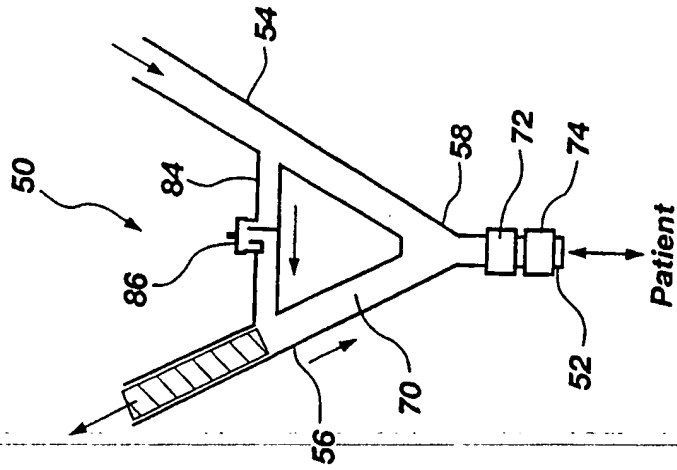


Fig. 5C

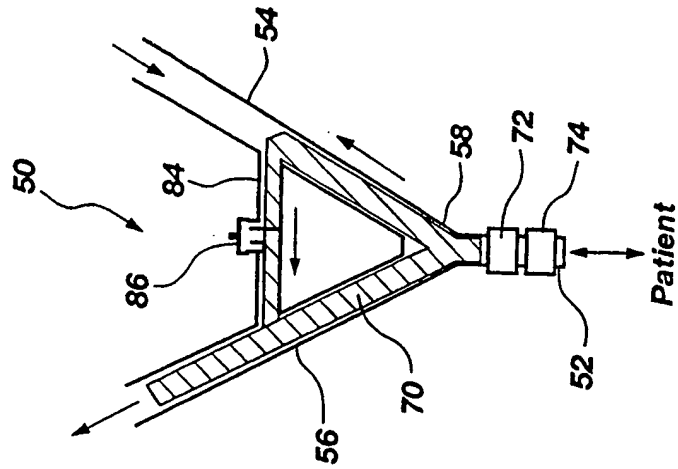


Fig. 5B

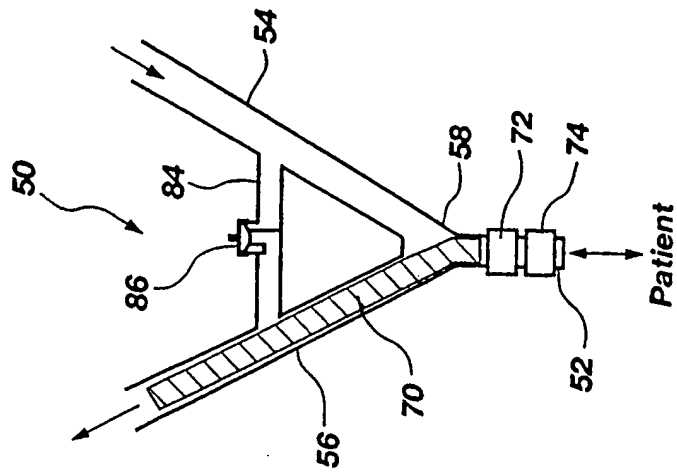
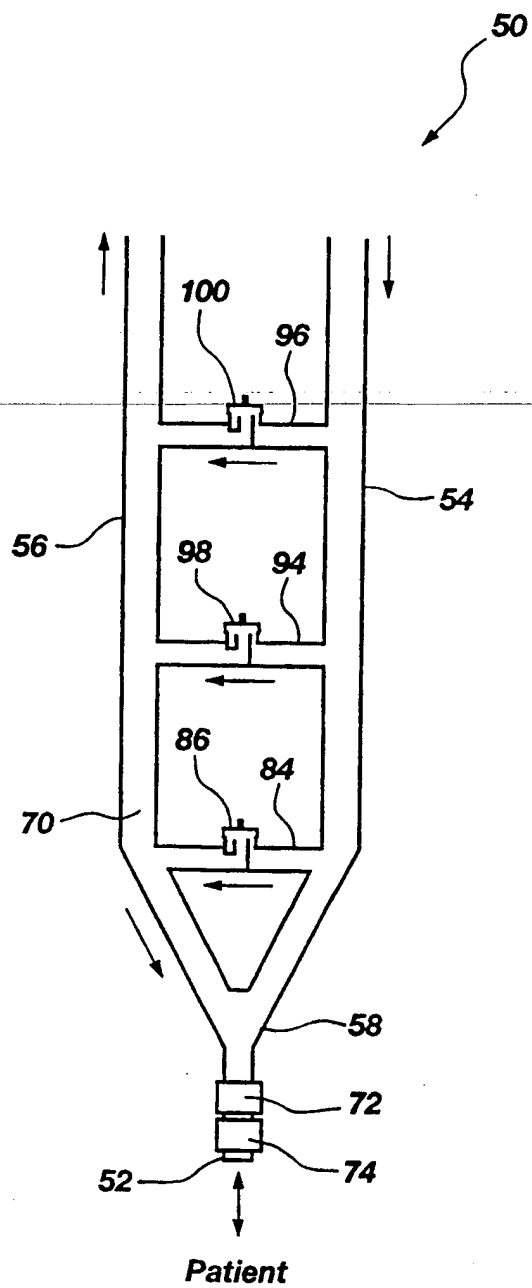
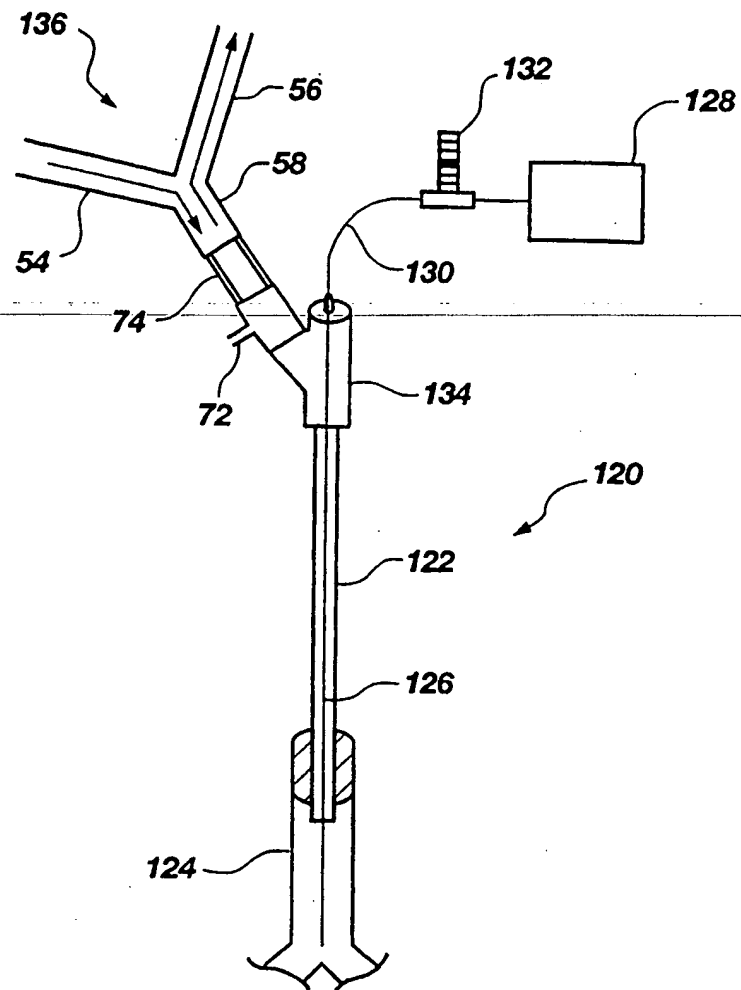


Fig. 5A

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**Fig. 7**

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**Fig. 9**

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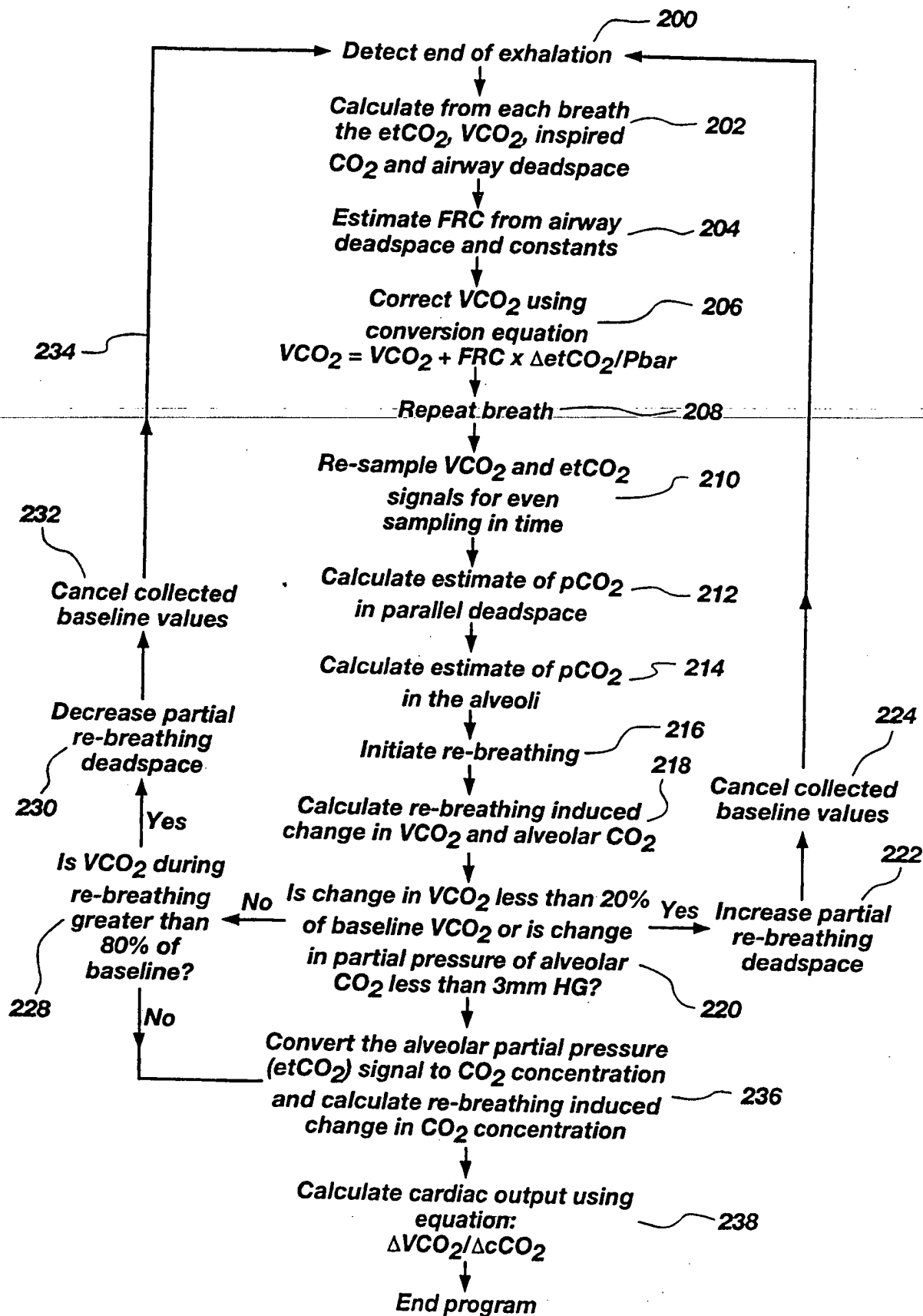


Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/24263

A. CLASSIFICATION OF SUBJECT MATTER:
IPC (6):

A61B 5/00

A. CLASSIFICATION OF SUBJECT MATTER:
US CL :

128/200.26,207.14,207.15, 207.16 ; 600/483,484,485,481,529,532,531,543